

In re Application of:

Campbell et al.

Application No.: 10/692,979

Filed: October 24, 2003

Page 6

Attorney Docket No.: PIED1110-1

REMARKS

A. Summary of the Invention and Claim Amendments.

Claims 1, 12, 34 and 39 are currently amended. Claims 5-7, 9, 11, 17-18, 20, 22-31 and 33 were previously canceled and Claims 8 and 41 are canceled herewith. After amendment, Claims 1-4, 10, 12-16, 19, 21, 32 and 34-40 are pending.

The claimed invention provides the art with the discovery that fatty acid esters, such as isopropyl myristate, can be used to rapidly kill ectoparasites as the *sole* ectoparasitidal agent; i.e., without application of other pediculocidal agents such as alcohol (per the Singer reference), an ectoparasiticidal amount of a siloxane (versus, per dependent claims 8 and 10, as well as 19 and 21 as a mere non-active carrier), or insecticides.

The amendments are supported in the Specification by paragraph 0011, which clearly teaches that isopropyl myristate can be utilized as the sole ectoparasitidal agent in the compositions of the invention; i.e., without a siloxane or insecticide:

“The present inventors discovered unexpectedly that just fatty acid esters alone, preferably isopropyl myristate, have the effect of killing ectoparasites....either [IPM or a siloxane] may be included in a composition in an amount effective for killing lice, fleas, ticks and other ectoparasites...” (emphasis added).

The recited ranges for the isopropyl myristate are set forth in Paragraph 0020. The Specification also supports the amendments by teaching that a siloxane may be provided in the invention as a carrier rather than as an ectoparasitidal agent (see, paragraph 0021).

In re Application of:

Campbell et al.

Application No.: 10/692,979

Attorney Docket No.: PIED1110-1

Filed: October 24, 2003

Page 7

No new matter being added to the Specification, entry of the proposed amendment is therefore requested. The Examiner's consideration of the claims as amended is appreciated.

B. Claims 1-4 and 16.

The Office Action summary indicates that Claims 1-4 and 16 stand rejected. However, no rejection stated in the Action is applied to these claims. It is therefore submitted that Claims 1-4 and 16 should stand allowed.

C. Response to Rejection under Section 112, First Paragraph.

Claims 2-3, 13, 14, 35, and 36 are rejected for lacking written description support with respect to use of isopropyl myristate as the sole killing agent without use of siloxane as a co-active agent (versus as a carrier). However, as noted above, the Specification clearly supports the claims in this respect. Reconsideration and withdrawal of the objection is therefore respectfully requested.

D. Response to Rejection under Section 102(b) or, alternatively 103, based on Singer
Claims 12-15 and 39-41 are rejected under Section 102(b) or, alternatively, 103, based on Singer, U.S. Patent No. 4,147,800.

The Office Action asserts that Singer teaches the use of isopropyl myristate (IPM) to kill ectoparasites at concentrations of 50 or 70%, and that it would have been obvious to one of ordinary skill in the art to omit alcohol from the Singer composition to avoid sensitivity thereto. However, such a teaching is not only entirely absent from Singer, the asserted reading of the reference contradicts what Singer does teach; i.e., that IPM is not effective except at toxic levels, and that it can only be effective when used in conjunction with an alcohol.

In re Application of:

Campbell et al.

Application No.: 10/692,979

Filed: October 24, 2003

Page 8

Attorney Docket No.: PIED1110-1

According to Singer, the alcohol is a necessary active that acts synergistically with IPM to enhance its activity:

[00007] **The pediculicidal toxicant of the instant invention is an admixture of an aliphatic alcohol and an aliphatic ester.** The combination is synergistic and retains its high level of activity when diluted in an inert pharmaceutically acceptable carrier, most notably an aqueous carrier.

To this end, Singer requires that an aliphatic alcohol be present in a concentration of at least 20% w/w as an active agent:

[00012]. . . . It has been found that an effective pediculicidal toxic amount can be obtained when the amount of the aliphatic alcohol in the treating composition is at least about 20 percent by weight and the amount of the aliphatic ester is at least about 15 percent by weight.

In contrast, IPM alone below the purportedly toxic level of 70% w/w is described as being *ineffective* to kill 100% of lice as presently claimed (see, Col. 4, lines 21-32). Use of an aliphatic alcohol is therefore a critical part of the Singer invention, not a merely optional additive, as suggested in the Office Action.

As such, the asserted reading of Singer that IPM can be used alone directly contradicts the explicit teaching of the reference, and reads into it a suggestion for forgoing use of alcohol that simply is not present in the reference. Singer cannot be reasonably read to suggest that the aliphatic alcohol described as a necessary synergist could be eliminated for any reason, much less to address sensitivity concerns. According to Singer, doing so would render the IPM ineffective. It is therefore only in hindsight that one can read Singer and surmise that, as presently claimed, IPM can indeed be utilized as the sole ectoparasitidal agent at levels of as little as 10% w/w to 70% w/w.

Furthermore, as the Office Action acknowledges, Singer demonstrates that few lice were killed by IPM at concentrations below the purportedly toxic level of 70% w/w. As such, Singer explicitly *teaches away* from the claimed limitation requiring that at least 50% of treated lice die within an hour (Claim 1) and as little as 10 minutes (Claim 34) of application.

Indeed, as to time, nothing in Singer suggests that killing can be obtained within less than about 24 hours of application:

[00012] The **alcohol-ester admixture** is incorporated into the composition used to treat the substrate in need of such treatment, believed to be in need of such treatment, or desired to be prophylactically protected in an effective pediculicidal toxic amount. By such amount is meant the amount which will cause virtually 100% of the lice exposed in the two or four minute immersion test described below to die **within 24 hours**.

The present claims all require that the IPM kill at least 50% of ectoparasites within an hour, and within as little 10 minutes. This is a critical finding of the invention not acknowledged by the Office Action's assertion that no criticality for the claim limitations has been shown.

In short, following Singer, one would conclude that (1) IPM is an ineffective ectoparasiticidal agent at non-toxic levels without use of a synergist, which synergist must be an alcohol whose use is excluded by the present invention, and (2) lice treated with the IPM-aliphatic alcohol combination of Singer would not die for 24 hours until after treatment. The invention teaches the opposite—IPM *is* an effective ectoparasitidal at non-toxic levels when used alone; i.e., without a synergist of any kind.

Moreover, according to the invention, IPM works far more rapidly than contemplated by Singer—within as few as 10 minutes, all treated lice can be killed. Contrary to the assertion of the Office Action that no activity differing from that of the prior art is possessed by the invention, the single agent rapid effect of IPM on ectoparasites is not at all contemplated by Singer.

Rather, it is clear that Singer teaches away from the claimed invention by *requiring* use of an alcohol as an active agent and by teaching that IPM can only be effective against ectoparasites when used by itself if applied at toxic levels. Singer further fails to suggest any rapid killing effect by IPM at any concentration. In short, Singer does not teach or suggest all of the limitations of the present claims, including the critical limitations drawn to use of *IPM as the sole killing agent*, effective against *up to 50%* of treated ectoparasites *within an hour* of application. As such, Singer cannot be read to anticipate the claimed invention and, given its teaching away from critical aspects, cannot be read to render it obvious either.

Reconsideration and withdrawal of the Section 102 rejection of Claims 12-15 and 39-40 are rejected under Section 102, based on Singer is therefore respectfully requested.

E. Response to Rejection under Section 103, based on Singer in view of Reid.

Claims 12-15, 32, and 39-41 are rejected under Section 103, based on Singer in view of Reid, U.S. Patent No. 5,972,987.

Reid is cited only for its teaching with respect to use of a comb. It does not cure any of the deficiencies of the Singer reference noted above.

Reconsideration and withdrawal of Claims 12-15, 32, and 39-40 are rejected under Section 103, based on Singer in view of Reid, is therefore respectfully requested.

In re Application of:
Campbell et al.
Application No.: 10/692,979
Filed: October 24, 2003
Page 11

Attorney Docket No.: PIED1110-1

CONCLUSION

All of the pending claims (1-4, 10, 12-16, 19, 21, 32 and 34-40) are believed to be in condition for allowance. In particular, Claims 1-4 and 16 appear to be free of any stated claim rejections and so are believed to be allowable. Further, the rejections stated as to Claims 10, 12-15, 19, 21, 32 and 34-40 are believed to be overcome for all of the foregoing reasons. Reconsideration of those claims rejections and allowance of all pending claims is therefore respectfully requested.

No fees are believed to be due in connection with the filing of this paper. However, the Commissioner is hereby authorized to charge any other fees that may be due in connection with the filing of this paper, or credit any overpayment to Deposit Account No. 07-1896, referencing the above-identified docket number.

Respectfully submitted,



Stacy L. Taylor
Registration No. 34,842
Telephone: (858) 677-1423
Facsimile: (858) 677-1465

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DLA PIPER LLP (US)
4365 Executive Drive, Suite 1100
San Diego, California 92121-2133
USPTO Customer Number 28213